K120545

OCT 2 3 2012

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5. 510(k) Summary

See 510(k) Summary, below.

1. Trade Name: HX-461
   Common Name: Auto Blood Pressure Meter
   Product Code: DXN (Blood pressure measurement monitor), OUG (Medical Device Data System)
   Regulation: 21 CFR 870.1130 & 21 CFR880.6310
   Class of device : ClassII.

2. The legally marketed device to which we are claiming equivalence: UA-789 & UA-767PBT(K043217)

3. Description of device:
   HX-461 applies the oscillometric method to measure patient blood pressure. It is composed of blood pressure module, cuff, LCD touch pad control panel and CPU processer based on Window CE to operate the blood pressure module. Patient can easily operate the device with the touch pad using the cuff installed in the device. Operator can control by touch screen based on SEERSTECHNOLOGY CO., LTD.'s software. It has unique communication function that can get the medical information from other blood pressure meter, blood glucose meter and body fat measurement device using bluetooth module and wire connector. HX-461 has a wire and wireless internet function.

4. Intended Use: HX-461 is intended for used by adults to measure the systolic and diastolic blood pressure and pulse rate and transfer medical device data electronically

5. Technological Characteristics:

The Device is investigated for function and effectiveness to compare the operation of function between HX-461 and the UA-789 & UA-767PBT.
Comparison results demonstrate that the specifications and performance of the device are same as functional and effective as the legally marketed predicate device.
Therefore, it is concluded that HX-461 is substantially equivalent to the legally marketed predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 23 2012

SEERS Technology Co., Ltd.
c/o Mr. Peter Chung
300 Atwood Street
Pittsburgh, PA 15213

Re: K120545
Trade name: HX-461 Auto Blood Pressure Meter
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: July 23, 2012
Received: October 19, 2012

Dear Mr. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

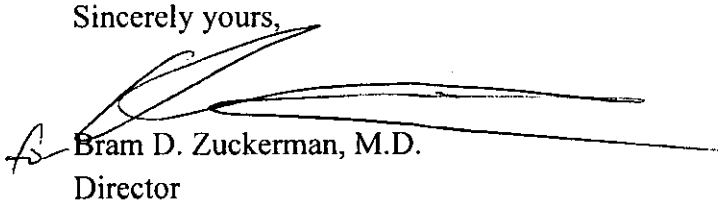
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120545

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K12

Device Name: HX-461

Indications For Use:

HX-461 is intended for used by adults to measure the systolic and diastolic blood pressure and pulse rate and transfer medical device data electronically to the designated health care center through internet website. HX-461 enables user registration for user-specific data management, and provides blood pressure measurement function. It can receive blood pressure, blood glucose and body fat measurement values by connecting with respective measurement instruments supporting Bluetooth connection, or by docking a blood glucose meter on its back. In addition, HX-461 supports wired/wireless communication with a designated person including video communication.. It has three size of cuff for blood pressure measurement. User chooses the cuff depending on their arm circumference.

Cuff size	Arm Circumference
D-cuff Small	: 18-22cm
D-cuff Adult	: 22-32cm
D-cuff Large	: 32-45cm

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120545